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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/023,839	12/21/2001	Richard Derose	022650-685	4793

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EXAMINER	
HELMER, GEORGIA L	

ART UNIT	PAPER NUMBER
1638	

DATE MAILED: 07/02/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/023,839	DEROSE ET AL.	
	Examiner	Art Unit	
	Georgia L. Helmer	1638	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on _____.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) 1 is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) 1 is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☒ Certified copies of the priority documents have been received in Application No. 09/000,062.

3.☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date *21 December 2001*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Status of the Claims

1. The Office acknowledges receipt of the Preliminary Amendment dated 21 December 2001, which amends claim 1 and cancels claims 2-24.

Claim 1 is pending and is examined in the instant action.

Information Disclosure Statement

2. Applicant's IDS filed 21 December 2001 is acknowledged and a signed copy provided herewith.

Priority

3. It is noted that this application appears to claim subject matter disclosed in prior Application No. 09/000,062, filed 29 May 1998, and PCT/FR96/01109, filed 17 July 1996. A reference to the prior application must be inserted as the first sentence of the specification of this application or in an application data sheet (37 CFR 1.76), if applicant intends to rely on the filing date of the prior application. For benefit claims under 35 U.S.C. 120, the reference must include the relationship (i.e., continuation, divisional, or continuation-in-part) of all nonprovisional applications. Also, the current status of all nonprovisional parent applications referenced should be included.

Claim Rejections - 35 USC § 112

4. The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

5. Claim 1 is rejected under 35 U.S.C. 112, second paragraph.

Claims 1 is drawn to " an isolated DNA sequence ...where said DNA sequence is the first intron (intron 1) of the 5' non-translated region of a plant H3.3 histone gene", however no frame of reference for is given for "the first". Does this mean the first in line going from the 5' end to 3' of the sequence? Or does it mean the first with respect to the translational start signal?

Correction/clarification is required.

Claim Rejections - 35 USC § 112-written description

6. The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claim 1 is rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

Claim 1 is drawn to " an isolated DNA sequence serving as a genetic regulatory element in a ...where said DNA sequence is the first intron (intron 1) of the 5' non-translated region of a plant H3.3 histone gene". Applicant does not describe this sequence in terms of the size of the DNA or specific structural features, or by specific nucleic acid sequence. Applicant does not describe a plant H3.3 gene, or what components, sequences and structural features, identity

a plant H3.3 gene. Applicants are claiming a genus of sequences, yet there is no description of the structural features that define the genus. Only Applicant's specific SEQ ID NOs 1-7 are disclosed.

The Federal Circuit has recently clarified the application of the written description requirement to inventions in the field of biotechnology. The court stated that, "A description of a genus of cDNAs may be achieved by means of a recitation of a representative number of cDNAs, defined by nucleotide sequence, falling within the scope of the genus or of a recitation of structural features common to members of the genus, which features constitute a substantial portion of the genus." *See University of California v. Eli Lilly and Co.*, 119 F.3d 1559; 43 USPQ2d 1398, 1406 (Fed. Cir. 1997). Furthermore, Applicants fail to describe structural features common to members of the claimed genus of polynucleotides. Hence, Applicants fail to meet either prong of the two-prong test set forth by *Eli Lilly*. Furthermore, given the lack of description of the necessary elements essential for serving as "a genetic regulatory element in a chimeric gene, wherein the sequence is the first intron of the 5' non-translated region of a plant H3.3. histone gene", it remains unclear what features identify such a polynucleotide. Since the DNA sequence, the "first intron (intron 1) of the 5' non-translated region of a plant H3.3 histone gene" is not described by specific structural features, the specification fails to provide an adequate written description to support the breath of the claim.

(See Written Description guidelines published in Federal Register/Vol. 66, No.4/Friday, January 5, 2001/Notices: p.1099-1111).

Claim Rejections - 35 USC § 112-enablement

7. The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

8. Claim 1 is rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

The claimed invention is not supported by an enabling disclosure taking into account the *Wands* factors. *In re Wands,* 858/F.2d 731, 8 USPQ2d 1400 (Fed. Cir. 1988). *In re Wands* lists a number of factors for determining whether or not undue experimentation would be required by one skilled in the art to make and/or use the invention. These factors are: the quantity of experimentation necessary, the amount of direction or guidance presented, the presence or absence of working examples of the invention, the nature of the invention, the state of the prior art, the relative skill of those in the art, the predictability or unpredictability of the art, and the breadth of the claim.

The claims are drawn to any isolated DNA sequence serving as any genetic regulatory element in a chimeric gene, where said DNA sequence is the first intron (intron 1) of the 5' non-translated region of any plant H3.3 histone gene". However, Applicant's provide and explicitly demonstrate the isolation of only the nucleic acid sequences identified in SEQ ID NO: 1-7. Applicant

provides insufficient guidance as to how to isolate, prepare, identify the nucleic acids other than the SEQ ID NO sequences.

Undue Experimentation would be necessary to isolate of the claimed sequences in plants other than maize and Arabidopsis thaliana. Introns range in size from 36 bp to greater than 100,000 bp (Sinbaldi et. al.) Where in the 5' UTR should one look—introns are highly variable in length, as are the 5' UTR sequences, and just looking for "the first intron", which would require comparison of the unprocessed transcribed mRNAs to the processed mature mRNA, without other information, would require probing sets of genomic libraries and cDNA libraries of any given plant with random probes, which is very substantial experimentation. Furthermore, the introns of Applicant's SEQ ID NO: 6 and 7 are relatively small, about 400 bp, and are AT-rich DNA , which means that heterologous probes will not hybridize stringently compared to GC-rich DNA regions. These characteristics of the claimed and non-exemplified DNA sequences would make identification of the desired sequences even more difficult. This is coupled with the fact that the claimed DNA intron is "the first intron", implying the existence of a "second" intron. So all the experimentation needed and described above would have to be at least doubled. Furthermore, the mere germ of an idea does not constitute an enabling disclosure, and the specification, not the knowledge of one skilled in the art must supply the enabling aspects of the invention. See Genentech, Inc. v. Novo Nordisk, A/S, 42 USPQ2nd 1001, 1005 (Fed. Cir. 1997).

Therefore, given the breadth of the claims; the lack of guidance and working examples; the unpredictability in the art; and the state-of-the-art as discussed above, undue experimentation would be required to practice the claimed invention, and therefore the invention is not enabled throughout the broad scope of the claims.

Double Patenting

9. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970);and, *In re Thorington,* 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

10. Claim 1 is rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1 and 2 of U.S. Patent No. 6,338,961. Claims 1 of the instant case is drawn to "[a]n isolated DNA sequence serving as a genetic regulatory element in a chimeric gene, wherein

said DNA sequence is the first intron (intron 1) of the 5' non-translated region of a plant H3.3 histone gene". Claim 1 of the issued case is drawn to "[a]n isolated intron 1 from a plant H3.3-like histone gene selected from the group consisting of SEQ ID NO: 6 and SEQ ID NO: 7, wherein said intron 1 serves as a genetic regulatory element in a chimeric gene which can be used for transformation of plants and allow the expression of the product of translation of the chimeric gene in the regions of the plant undergoing rapid growth. Therefore the claim of the instant case is broader, having fewer limitations and being drawn to no specific sequence, than claim one of the issued case.

11. Although the conflicting claims are not identical, they are not patentably distinct from each other because the species claims of patent 6,338,961 renders the genus claims of the instant application obvious.

Remarks

12. No claim is allowed.

13. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Georgia L. Helmer whose telephone number is 571-272-0976. The examiner can normally be reached on 8:30 - 5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Amy Nelson can be reached on 571-272-0804. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

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Art Unit 1638
23 June 2004

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